

**IN THE UNITED STATES COURT
FOR THE MIDDLE DISTRICT OF ALABAMA**

CLIFFORD BAILEY , et al.)	
)	
Plaintiff,)	
)	
vs.)	3:06- CV-00979-MHT
)	Removed from the Circuit Court
)	Randolph County, Alabama
MERCK & CO., INC., ET AL.)	CV-06-145
)	
)	
Defendants.)	
)	

RESPONSE TO MOTIONS TO DISMISS

Now come the plaintiffs and respond as directed by the Court to the Motions to Dismiss filed on behalf of the sales representative defendants in this civil action and show the Court as follows:

A Motion to Dismiss is governed by Rule 12(b)(6) of the Federal Rules of Civil Procedure. Under this Rule, a Complaint should not be dismissed unless it fails to state any claim upon which relief can be granted. The Courts have applied an extremely liberal standard to pleadings under this Rule, and a civil action is rarely to be dismissed under Rule 12(b)(6). The Eleventh Circuit has routinely held:

“We review *de novo* a district court's dismissal of a complaint for failure to state a claim pursuant to Fed.R.Civ.P. 12(b)(6), construing the complaint in the light most favorable to the plaintiff and accepting as true all facts which the plaintiff alleges.

See Hishon v. King & Spalding, 467 U.S. 69, 73, 104 S.Ct. 2229, 81 L.Ed.2d 59

(1984); *see also Wright v. Newsome*, 795 F.2d 964, 967 (11th Cir.1986). The district court may only grant a Rule 12(b)(6) motion to dismiss where it is demonstrated ‘beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief.’ *Conley v. Gibson*, 355 U.S. 41, 45-46, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957).” *Day v. Taylor*, 400 F.3d 1272, at 1275 (11th Cir.2005).

In *Horsley v. Feldt*, 304 F.3d 1125, 1134 (11th Cir.2002), the Eleventh Circuit held that the court may consider a document attached to a motion to dismiss without converting the motion into one for summary judgment if the attached document is (1) central to the plaintiff's claim and (2) undisputed. In this context, “undisputed” means that the authenticity of the document is not challenged.

If Defendants are allowed to go outside of the pleadings for purposes of the 12(b)(6) motion, then it should be noted that there is very substantial evidence against Merck sales representatives and against the sales representatives in this case. Attached are copies of their “call notes” and other materials. The individual Defendants are sales representatives of Merck. We generally refer to them in this Response as the “sales representative Defendants”. Judge Hopkins of this Court recently wrote the attached opinion in a pharmaceutical case that included both the sales representatives and the manufacturer as Defendants. (attached as **Exhibit**

A)¹ Judge Hopkins found, in circumstances similar to those in the present case, that the plaintiff had stated a claim for which relief can be granted against the sales representative Defendants. She also found to the higher standard that there was a reasonable possibility that the Plaintiffs might be able to prove their claim against the sales representative Defendants.

Just to be very clear, when we attach and refer to the points made by Judge Hopkins we also mean to note that she followed this Court in holding that there was at least a possibility that an AEMLD claim would be valid against the sales representatives under Alabama law. We discuss that in greater detail in the Motion to Remand filed with this Response to the Motions to Dismiss.

Also in Exhibit A are other Merck Vioxx cases where sales representatives were found not to be fraudulently joined, or due to be dismissed without the normal processes of law. Without any intention of overburdening this Court with evidence at this very early stage of this litigation, we attach to this Response a number of documents indicating that this is not the type of situation of a weak or token claim. Instead, these Merck sales representatives are “up to their eyeballs” in available evidence against them, early in this case, coming out of the starting box.

For example, we have the unusual benefit that the U.S. House of Representatives Committee on Government Reform released a memorandum

¹ We use one set of Exhibits for the Motion to Remand and this Response.

entitled “The Marketing of Vioxx to Physicians.” (Attached hereto as **Exhibit B**)

This report will be discussed subsequently in greater detail, but suffice it to say that the report is damning of the methods employed by Merck through its sales representatives to vigorously promote Vioxx to prescribing doctors despite its known cardiovascular risks associated with the drug. This report confirms that the sales representatives for Merck were not mere lackeys. This force of 3,000 people, including the defendants herein, was a well-trained, organized, and aggressive group. Most importantly, it was a group armed with the knowledge of the risks associated with Vioxx and tediously trained to misinform, misinterpret, dodge, and obfuscate those risks. Their compensation could be greatly magnified if doctors pushed their drugs - here, Vioxx. (See **Exhibit L**)

Of course, in considering an early 12(b)(6) dismissal, a District Court, under the Federal Rules system, is to weigh heavily in favor of allowing the claim. If the court finds that there is some possibility of the Plaintiffs stating a claim against the Defendants in question, and being able to prove such a claim, then the court is, under applicable law, to, at the very least, allow full discovery on the merits before unceremoniously tossing out a case on a one-paragraph initial motion to dismiss. The Plaintiffs in this case would certainly request a full opportunity to discovery on the merits as against any such Defendants and would request that this motion be denied as contemplated by Federal Rules 12(b)(12).

The Federal and Alabama Rules on the subject are substantially identical,

and both sets of cases follow the same procedure for this type dispute. In *Phillips v. AmSouth Bank*, 833 So.2d 29 (Ala.2002), plaintiffs brought an action against the bank for breach of fiduciary duty and misrepresentation. The Circuit Court, Shelby County granted bank's "motion to dismiss." The plaintiffs appealed, and the Alabama Supreme Court, Woodall, J., held that the plaintiffs were entitled to discovery, as the motion was actually to be treated as one for summary judgment.

The Court held that plaintiffs were entitled to conduct discovery, in the action against the bank for breach of fiduciary duty and misrepresentation, in that the bank turned its motion to dismiss into a motion for summary judgment by submitting affidavit of bank vice president.

The Alabama Supreme Court adopted the statement that "because the trial court dismissed the case on AmSouth's [Ala. R. Civ. P.] 12(b)(6) Motion which included a substantive affidavit, [it] committed reversible error by prohibiting discovery regarding AmSouth's factual assertions." 833 So.2d 29, at 31. The Court went on to say:

"The text of Rule 12(b) is clear and *obligatory*-when a motion to dismiss is converted to a motion for a summary judgment, the motion shall be "disposed of as provided in Rule 56[, Ala. R. Civ. P.]," and the nonmovant " *shall* be given *reasonable opportunity* to present all material made pertinent to such a motion." (Emphasis added by the Court.) Discovery was held to be essential to this opportunity. All of these holdings are based on identical language in Federal Rules 12 and 56. Indeed, the Federal Courts have long established the procedure, for example in *Arrington v. City of Fairfield*, 414 F.2d 687, at 693 -694 (5th Cir. 1969)

the Court ruled:

“The District Court erred in granting defendants' motions to dismiss and for summary judgment. Defendants should be required to file answers and the parties allowed to undertake discovery pursuant to the Federal Rules of Civil Procedure. We, therefore, remand this case to the District Court for proceedings consistent with this opinion. Reversed and remanded.”

The law, therefore, is strongly in favor of allowing this case to go forward with discovery and other proceedings on the merits; so are the facts:

Merck’s Internal Documents Confirm that Sales Representatives Were Trained to (and did) Mislead and Conceal Cardiovascular Risks from Physicians.

Merck has alleged that federal jurisdiction exists in this case because its sales representatives were fraudulently sued and joined. Nothing could be further from the truth. The undisputed evidence leads to the inescapable conclusion that Merck knew of cardiovascular risks, at the latest, in 2000, and that Merck trained its sales representatives to intentionally mislead physicians who posed questions concerning cardiovascular side effects. The call notes show that these sales representatives carried the Vioxx false message to the relevant doctors- accompanied even by a cash honorarium! (**Exhibits**)

In early 1999, Merck started an 8,000 person trial referred to as the Vioxx Gastrointestinal Outcomes Research Study (VIGOR). This trial compared Vioxx with naproxen, and excluded from the group, people who had cardiovascular problems within a year of the sample.

In March, 2000, less than one year after the FDA approved Vioxx, the results of the VIGOR trial indicated that Vioxx caused *four times* as many heart attacks as the Naproxen group. The results of the VIGOR trial caught the attention of the FDA and many in the medical research community, but Merck

attempted to neutralize the results of the trial by claiming that Vioxx looked bad in comparison to naproxen because naproxen was “cardio protective,” a position which credible epidemiologists would deem untenable.

In any event, following the VIGOR trial, Merck scrambled in an attempt to address concerns from prescribing physicians which would inevitably follow the results of the VIGOR trial. Merck made a conscious decision to train its sales representatives to mislead, misrepresent, conceal, and “dodge” questions from physicians about the cardiovascular risks associated with Vioxx.

Attached hereto as **Exhibit F** is a Merck internal document revealing the despicable manner in which Merck trained its sales force after the results of the VIGOR trial were announced. This document is entitled “Dodgeball Vioxx.” The document lists various “obstacles” which the sales rep is trained to overcome. These “obstacles” are nothing more than the anticipated questions of prescribing physicians. This court may recall from other litigation, that physicians heavily rely on sales representatives who are supposed to furnish accurate information regarding the properties of the drugs they detail. Physicians rely on this information in their treatment of patients. Merck also creates a sort of “buzz” about a drug in the medical community by involving local doctors as opinion leaders.

This (**Exhibit F**) document is revealing because it confirms Merck’s scheme to have its sales representatives obfuscate as much as possible the issue of cardiovascular risks associated with Vioxx. Indeed, in the document, it notes the following:

“The competition has been in my office telling me that the incidence of heart attacks is greater with Vioxx than with Celebrex.”

The training manual also includes “obstacle four” which states as follows:

“I am concerned about the cardiovascular effects of Vioxx?”

At the end of these training materials, the Merck sales representative is provided instructions on how to answer each and every question, or “obstacle” contained therein. The Merck sales representatives are instructed to “DODGE!”

On November 9, 2004, the United States Committee on Government Reform requested that Merck provide the Committee with a range of documents related to Vioxx in preparation for the May 5, 2005 hearing on FDA and Vioxx® (in a letter from Chairman Tom Davis to Merck Chief Executive Officer Ray Gilmartin dated November 9, 2004)

A Memorandum was prepared in Congress to members of the Government Reform Committee concerning the marketing of Vioxx to Physicians, dated May 5, 2005. Over 20,000 pages of Merck documents were reviewed evidencing that the company used its sales force to counter the concerns of safety of Vioxx. A copy of this Memorandum is attached hereto as **Exhibit B**.

This Memorandum and Executive Summary shed further light on the distressing tactics of Merck. Nothing was left to the imagination of the sales force marketing this drug. The Executive Summary stated:

“The documents indicate that Merck instructed these representatives to show physicians a pamphlet indicating that Vioxx might be 8 to 11 times safer than other anti-inflammatory drugs, prohibited the representatives from discussing contrary studies (including those financed by Merck) that

showed increased risks from Vioxx, and launched special marketing programs - named Project Xxceleration and Project Offense - to overcome the cardiovascular obstacle increased sales.”

(Waxman Memorandum to Members of the Government Reform Committee, May 5, 2005, p.3)

Indeed, the 3,000 person sales force Merck used to promote Vioxx was very well trained. The Merck training manual (Merck, *Professional Presence*, undated, attached hereto as **Exhibit G**), promoted that “gaining access and building relationships... are key to providing you the opportunity to influence your customers’ behavior”. Another manual, (Merck, *Selling Skills for Hospital Representatives & HIV Specialists*, undated, attached hereto as **Exhibit H**), instructed them on how to close the deal. The materials and manuals provided the sales force were extensive, and nothing was left uncovered; other topics included selling skills (*Selling Skills* attached as **Exhibit H**) ; using and reading nonverbal techniques (Merck, *Captivating the Consumer*, June, 2001, attached hereto as **Exhibit I**); assessing the personality of doctors in order to determine what type of information would be most convincing to them (Merck, *Champion Selling: Milestone Leader’s Guide*, January, 2002, attached hereto as **Exhibit J**); refocusing conversations from non-business subjects to business subjects (Merck, *Planning, Conducting & Following up Successful HEL Programs*, 1999, attached as **Exhibit K**); and, detailing how to give handshakes and greetings and how to eat when dining with physicians (Merck, *Professional Presence*, undated, attached as **Exhibit G**). These examples show how determined Merck was to focus the tactics

of its sales force on pushing Vioxx on all Physicians. There is every reason to believe that these sales representatives carried this out here.

Merck provided its sales force with detailed instructions on a range of sensitive subjects specific to the marketing of its drugs, including Vioxx®. They were provided with specifics on individual doctors' prescribing habits and were to use this data to increase their prescribing of Merck drugs. This data was purchased from outside sources that tracked pharmacy prescriptions (Merck, *Data Sources*, May, 2003). Further, Merck could compile monthly reports on overall sales and market share for each sales representative's territory, and the representatives were instructed that their bonuses were to be based on overall sales figures (Merck, *Basic Training Participant Guide*, January, 2002, attached hereto as **Exhibit L**). The sales representatives were instructed on how to approach getting hospitals to add Merck drugs onto their formularies, thereby making it more likely that their products would be used (Merck, *Hospital Strategy Simulation: Roleplayers Guide*, September, 2000, attached as **Exhibit M**). Additionally, Merck also instructed its sales force on the use of speaker programs and educational events to enhance the sale of its products. The sales force knew which speakers would speak favorably about Merck's products and whether they were influential among their peers (Merck, *Specialty Foundations Participant Self-Study Workbook: Specialty Representative Advocate Development*, May, 2001, attached hereto as **Exhibit N**).

The Waxman Memorandum reviewed the series of studies and news reports, discussed previously, in depth. Throughout the Merck documents a common theme emerged; the reassurance of physicians about the safety of Vioxx by providing highly questionable and misleading information about cardiovascular risks.

After the VIGOR Trial showed a five-fold increase in the risk of heart attacks for patients on Vioxx, Merck instructed its sales force to show doctors a

pamphlet suggesting that Vioxx was 8 to 11 times safer than other anti-inflammatory drugs, using studies that were not appropriate for an analysis of cardiovascular safety. The sales force was issued a “new resource” “to ensure that you are well prepared to respond to questions about the cardiovascular effects of Vioxx”. This was the “Cardiovascular Card”. (Merck, *Bulletin for Vioxx: NEW RESOURCE: Cardiovascular Card*, April 28, 2000, attached hereto as **Exhibit O**) The data on this card had little or no scientific validity.

On May 1, 2000, Merck provided a bulletin to “all field personnel with responsibility for Vioxx”. (Merck, *Bulletin for Vioxx: New Obstacle Response*, May 1, 2000, attached hereto as **Exhibit P**) This bulletin told the sales force how to respond to a Pfizer, a competitor’s, argument that “Vioxx has an increased incidence of heart attacks compared to Celebrex.” (Merck, *Bulletin for Vioxx*) This involved using the “Cardiovascular Card”. Note that these particular sales representatives were specifically combating Pfizer here. (**Exhibits**)

As a result of the February 2001 meeting of the FDA Arthritis Advisory Committee, the Committee voted that doctors should be informed of the data from the VIGOR study. The next day, Merck sent another bulletin to “all field personnel with responsibility for Vioxx.”, instructing them to “stay focused on the EFFICACY messages for VIOXX”. (Merck, *Bulletin for Vioxx: FDA Arthritis Advisory Committee Meeting for Vioxx*, February 9, 2001, attached hereto as **Exhibit Q**) The bulletin stated:

DO NOT INITIATE DISCUSSIONS ON THE FDA ARTHRITIS
ADVISORY COMMITTEE...OR THE RESULTS OF THE...VIGOR STUDY

Sales force staff were given detailed steps to take when physicians asked about these topics.

After the August 22, 2001 study published in the *Journal of the American Medical Association* (D. Mukherjee, S. Nissen, E. Topol, *Risk of Cardiovascular Events Associated with Selective Cox-2 Inhibitors*, *Journal of the American Medical Association*, 954-9, August 22-29, 2001) which raised serious concerns about the safety of Vioxx and other drugs in the same class, Merck urged its sales force to show confidence in Vioxx's cardiovascular safety and to use the Cardiovascular Card. In light of this study, Merck Executive Jo Jerman left a voice mail for all the company's field representatives, urging them to : "Stay focused. Stay focused with your efficacy and GI risk awareness messages and stay focused with your confidence in cardiovascular safety and overall safety of Vioxx" (Merck, *MVX for Vioxx, Field Sales - USHH, Jo Jerman, August 21, 2001 "JAMA article" FINAL (approx 4 minutes)*, August 21, 2001, attached hereto as **Exhibit R**). Instead of moderating its sales approach, Merck launched a new marketing strategy, Project Offense. This strategy focused on efficacy. If "obstacles" appeared when discussing physicians, the sales force was to "quickly and effectively address all physician obstacles and return to the core message for Vioxx." (Merck, *Project Offense Meeting Agenda & Content: Representative Meetings*, 2001). The Defendants followed these commands (Exhibits)

Accordingly, the sales representative defendants are liable to the Plaintiff for the claims stated herein; these sales representatives were not duped by Merck. They willingly participated in this sordid scheme. They went on to "Project Offense" when the dangers were known, and did so to increase their bonuses.

It is clear from these materials that Merck and its sales force engaged in a scheme to defraud prescribing physicians, with the intent that patients not be told about the cardiovascular risks associated with Vioxx. Merck trained its sales force to "dodge" life-saving questions from physicians. The sales force, including the individual Defendants in this case, knowingly concealed and misrepresented the cardiovascular risks of Vioxx from prescribing physicians.

Far from being immune from liability or fraudulently joined, the sales representatives who participated in this scheme are liable for several common law causes of action in Alabama.

CONCLUSION

Plaintiffs request that the Motions be denied.

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CERTIFICATE OF SERVICE

I hereby certify that I have this 22nd day of November, 2006, electronically filed and served through CMECF a copy of the forgoing upon:

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